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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,678	12/07/2001	Glenn J. Gormley	19109DE	1340

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,678

Applicant(s)

GORMLEY ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 28-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: .

DETAILED ACTION

Response to Arguments

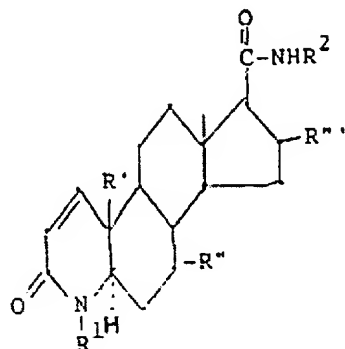
1. Applicant's arguments filed Nov.06/2002 have been fully considered but they are not persuasive. The detailed response to the argument will be following after brief summary of previous office action.

Claim Rejections - 35 USC § 102

1. Claims 28-29 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmusson et al (EP 0285382 A2).

Rasmusson teaches a treatment of androgenic alopecia using topical 5 alpha reductase inhibitors(e.g.17-beta-N-monosubstituted-carbamoyl-4-aza-5alpha-androst-1-ene-3-ones) such as in the form of cream, lotion or ointment, see examples and claims. Rasmusson also teaches the limitations recited in claims 29 and 34 (i.e. a treatment of male pattern baldness) and the species required by claim 33 (i.e. 17 β -(N-tert-butylcarbamoyl)-4-aza-5 α -androst-1-ene-3-one) as a preferred species, see abstract; page 2, line 47; examples 6-12 and claims 1-4 and 6-8. It also teaches the patented compounds having the formula found in patented claim 1 as follows:

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(wherein:

R¹ is hydrogen, methyl or ethyl;R² is a branched chain alkyl of from 3-12 carbon atoms;

R' is hydrogen or methyl;

R'' is hydrogen or β -methyl;R''' is hydrogen, α -methyl or β -methyl) for the manufacture of a medicament useful for treating androgenic alopecia.

The formulas I and II required by the instant claims 31 and 32 are encompassed by the patented formula shown above(supra). Even though the instant claims use the term "5 α -reductase 2 inhibitor" whereas Rasmusson(EP'382) uses the term "5 α -reductase inhibitor", they are considered to be the same or inherently same since they have same structure and utility. All the critical elements required by the instant claims are taught by the cited reference. Thus, all the claimed subject matter is rejected over the prior art of the record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmusson et al (EP 0285382 A2) in view of Goldman(US 5,407,944).

Rasmusson et al's teaching is mentioned in 102 rejection. For instance, the examples and claim 8 teach various alternative topical formulations including solution, cream, ointment, gel, shampoo or aerosol. Rasmusson teaches most elements required by the instant claims 30 and 35-37 except a topical application being formulated in the form of a transdermal skin patch.

However, it would be obvious to one of ordinary skill in the art to make a transdermal skin patch comprising a 5 α -reductase 2 inhibitor to treat androgenic alopecia(e.g. male pattern baldness) when Rasmusson's reference is modified with Goldman because Goldman suggests that a pharmaceutical preparation could be made in the form of a topical transdermal skin patch comprising a composition containing 5 α -reductase 2 inhibitor (e.g. finasteride®), see column 6, lines 10 and 20, especially line 28 and claims. For instance, Claims 17 and 19 contemplates a method for promoting hair growth using topical application of a vasodilator in combination with a 5 α -reductase inhibitor. In addition to the techniques for formulating a transdermal patch from the topical formulations is generally well within the skilled level of the artisan having ordinary skill in the art, one would have had the reasonable expectation of success for treating androgenic alopecia by utilizing a skin patch formulation of 5 α -reductase 2 inhibitor as an active component as suggested in Goldman. Thus, one would have been motivated to modify Rasmusson's teaching to include a transdermal skin patch to extend the applicability and acceptance by the patient who prefers a patch

application to fit their needs, wherein the increased compliance would enhance the therapeutic efficacy and achieve cost-effective treatment via short duration of therapy and because this is seen as an alternative means to deliver medications. It is noted that finasteride® is 17 β -(N-tert-butylcarbamoyl)-4-aza-5 α -androst-1-ene-3-one.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

.....

Response to the arguments

4. Applicant's arguments against 102 and 103 rejections are not persuasive.

Firstly, in response to the argument regarding transdermal application, the term "transdermal" includes any application that is applied through the unbroken skin(refers to mediations applied directly to the skin(creams, ointments, patch, etc), see dictionary, World net 1.7 or Webster(copies are enclosed in PTO-892). Topical compositions(i.e. cream, lotion, ointment) taught by the Rasmusson encompass the critical element required by the instant claims(i.e. transdermal application). Thus, claims 28-29 and 31-34 are anticipated by the Rasmusson reference and the rejection is maintained.

5. Secondly, Applicant argues that the skin patch containing 5-alpha reductase inhibitor is not specifically taught by Goldman(US 5407944). However, this examiner would not agree on applicant's argument because the patented claims 17 and 19 which are directed to the combination of vasodilator and 5-alpha reductase inhibitor in topical

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preparation that could be formulated in skin patch in light of the patented disclosure (column 6, lines 10-20). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention made to modify Rasmusson's teaching with Goldman's to make skin patch composition to increase the selection option and the improve the quality of the therapy by enhancing the compliance wherein the extended formulation would benefit the patient and fit the patient's need.

6. Regarding Double Patenting(DP) rejection, this examiner is decided to withdraw DP rejections since applicant's argument is persuasive.

Conclusion

7. All the pending claims 28-37 are maintained in the rejection.

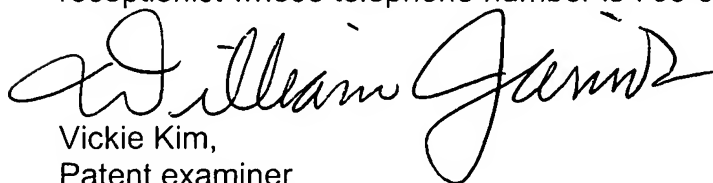
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

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The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "Vickie Kim", written in a cursive style.

Vickie Kim,
Patent examiner
January 16, 2003
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